Remarks/Arguments

The Applicants would like to thank Examiner McKane for taking the time to interview with Applicants' counsel on October 16, 2006. Her cooperation and effort is greatly appreciated.

As first set forth in an Advisory Action mailed September 12, 2006, and further discussed during the interview, the Examiner asserted that the "it is simply not patentable to take the invention of Nicolais and merely add an inert atmosphere to the outer envelope specifically as Ahlqvist et al. recognizes that polymeric packaging materials themselves experience degradation in the presence of oxygen when exposed to gamma (γ)-radiation." However, there are significant differences in the packaging materials disclosed in the Alhqvist reference and the materials of the sachet of the claimed invention. In light of these differences, Ahlqvist should be removed as a secondary reference, as discussed in detail below.

Both the present application and the Ahlqvist reference discuss the problems associated with using gamma (γ)-radiation to sterilize polyethylene medical implants. In fact, as apparent from both the Ahlqvist reference and the present application, it

is well-known that if polyethylene implants are exposed to radiation while a gaseous atmosphere surrounding the implants contains oxygen, then the polyethylene material is subject to oxidation and degradation.

As set forth in Ahlqvist, like the polyethylene implants, packaging *made from similar materials* will also degrade when exposed to gamma (γ)-radiation. Thus, the Ahlqvist reference is directed to the use of gamma (γ)-radiation to sterilize packaging materials *made from materials similar to polyethylene*. Specifically, Ahlqvist is directed to "a gamma-radiation sterilized medical article made of a polymeric material and a gamma-radiation sterilized container made of a polymeric material containing a radiation sterilizable medical product" (See column 5, lines 60-64). Further, as set forth at column 6, beginning at line 48 of the specification, to sterilize the polymeric material, a "gas impermeable package containing the polymeric medical article or the polymeric container filled with a product for parenteral administration can optionally sealed in a oxygen depleted atmosphere in the presence of nitrogen or other suitable inert gas." Thus, according to the Examiner, Ahlqvist teaches providing an inert atmosphere to protect against the amelioration of *polymeric materials* during gamma (γ)-radiation and according

to the Examiner, is cited as teaching protection of polymeric packaging materials only. In this respect, the Examiner agreed that if the claims were narrowed to non-polymeric materials, then Ahlqvist would be removed as a secondary reference, as set forth in the Interview Summary.

However, it is respectfully submitted that the issue should not be whether or not the packaging material is polymeric, but rather, if the polymeric material is at least partially permeable so as to be subject to degradation by radiation. As further explained in Ahlqvist, the container is "preferably made of EVOH, polypropen, polyethylene, EVA, Excel®, Nylon-11, or other polymeric materials which are *partially gas permeable*. Therefore, at best, Ahlqvist teaches providing an inert atmosphere to protect against the amelioration of *at least partially gas permeable* polymeric materials during gamma (γ)-radiation.

In stark contrast to the Ahlqvist container, the container or sachet of the present invention must be *gas impermeable*, as discussed in the specification and required by at least claim 1. Since the claimed sachet is made from a gas impermeable material, Alhqvist should be removed as a secondary reference.

Not only does the combination of the Nicolais and Ahlqvist references lack a teaching of every claim limitation, namely a gas impermeable sachet, as discussed above, but there is also no motivation to combine the Nicolais and Ahlqvist references. In contrast, the disclosures of the Nicolais and Ahlqvist references actually teach away from their combination. While it might be possible to combine disclosed inventions of prior art references, the patent laws require more than just a possibility of the combination. There must be some motivation or suggestion to combine the teachings of the references. Without such motivation or suggestion, the possibility of combination is only determined by impermissible hindsight. Since there is no motivation or suggestion to combine the Nicolais and Ahlqvist references, withdrawal of the rejection premised on this combination is respectfully requested.

Nicolais teaches first placing an object in a package under vacuum and thereafter placing the package in an outer package. Further, according to Nicolais, the packaging material is made from a flexible, *low permeality material*, such as polyester film, linear-low density polyethylene film, ethylene vinyl acetate, ionomer, and nylon. Nicolais does not teach the use of any gas

impermeable packaging materials. Moreover, as indicated by the Examiner, Nicolais does not disclose using an inert atmosphere to protect polymeric material from degradation during radiation.

Not only does Nicolais lack a teaching of using an inert atmosphere to protect polymeric material from degradation during radiation, but Nicolais actually teaches away from the use of gamma (γ)-radiation sterilization. Nicolais expressly discloses packaging materials made from *low permeability material*. As discussed above, polymeric materials, namely gas permeable polymeric materials, degrade when exposed to gamma (γ)-radiation. Thus, to avoid such amelioration, certain materials that do not degrade upon exposure to gamma (γ)-radiation, such as gas impermeable polymers, must be used. Accordingly, since Nicolais is silent with regard to the use of gas impermeable polymeric packaging materials, it cannot suggest a combination of the disclosed packaging method and the use of radiation for sterilization.

Further, and as previously pointed out to the Examiner, Ahlqvist lacks a motivation or suggestion to combine its teachings with the method of Nicolais. According the Ahlqvist, "[a]n important advantage of the invention is the possibility of

sealing the gas impermeable package in air, without the use of inert gases, and still be able to obtain an advantageous γ-radiation sterilization without side reactions." To obtain this purpose, Ahlqvist discloses placing oxygen scavengers within a gas impermeable package. Since Ahlqvist suggests using an oxygen scavenger instead of a vacuum, Ahlqvist teaches against combination with the method of Nicolais, which expressly teaches the use of a vacuum. Thus, since neither Nicolais nor Ahlqvist provides a motivation or suggestion to combine the references, withdrawal of the rejection based on this combination is respectfully requested.

Also unlike Ahlqvist, the present invention is not directed toward expanding the number of applications that utilize sterilized polyethylene products. As discussed during the interview, the present invention is directed to a packaging system for medical implants that maintains a sterile environment for the implants during transportation, even if the sachet containing the implant is damaged or otherwise compromised during shipment. To do so, the present invention teaches placing a medical implant in a sachet, drawing a vacuum within the sachet, and then sealing the sachet. The sealed sachet containing the implant is thereafter placed into a gas impermeable envelope, and

an inert gaseous environment is created in the envelope, after which the envelope is sealed. Lastly, the implant within the sachet is sterilized by radiation. Thus, if the sachet becomes damaged during transportation, the medical implant is still protected by the inert atmosphere.

As noted in the Background of the Invention section of the present application, "it remains delicate as it is difficult to guarantee the long-term tightness of the package, particularly during transport thereof, the least defect in closure of the sachet or the presence of a fragilized zone of the sachet compromising the sterile packaging of the implant." (See paragraph beginning at line 26 of page 1.) With the packaging process of the present invention, two additional advantages are achieved which are not suggested nor implied from either Nicolais or Ahlqvist. The first, mentioned above, is to protect the implant in the event that a leak occurs in the sachet, and the second is to provide a cushioned package to protect the implant as it is handled during shipment. As stated in the paragraph beginning at line 16 of page 7, "[t]he inert gaseous atmosphere formed by argon in the sterile packaging 1 thus obtained both ensures for the polyethylene implant a barrier against the ambient air, particularly the oxygen it contains, in particular

in the event of the tightness of the inner sachet being broken, and provides a function of immbolization ensuring shock absorption when the packaging is transported. Thus, instead of being directed to a method of sterilization, the present invention is directed to a method of packaging a medical implant that maintains a sterile environment for the implant.

In view of the foregoing differences between the prior art and the teachings of the present invention and the lack of the references to appreciate the motivation behind the process steps of the present invention, reconsideration of the 35 U.S.C. § 103(b) rejection for obviousness is respectfully requested and favorable consideration and allowance of the claims solicited.

Respectfully submitted,

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